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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,703	07/20/2001	Bruce J. Barclay	VASC 1020-2	2083

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/910,703

Applicant(s)

BARCLAY ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 18, 28-37, 58, 63-73 and 79-100 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-17, 19-27, 38-57, 59-62 and 74-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7, 10, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, a stent and Species II, the inner surface in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 13,14,18,28-37,58,63-73,79-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, species, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: first applying a protective layer to the coiled body.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,2,5,7,9, 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwin (6358276). Figs. 1,4 and 11a-c all show a coiled stent body. Edwin discloses that the stent is made from a metal, such as nitinol, col. 5, lines 8-9. Edwin also discloses delivering a drug to a site with a stent having a porous covering thereon with the drug between the stent and PTFE covering, col. 2 lines 50-54. Edwin also discloses means for delaying the drug to be released in the form of a sheath, col. 5, lines 14-16.

Claims 1-3,5-7,9,10,12,15-17,26,27,38-41,43,45,47,55-57,59,60-62,74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Razavi (5676685). Figs. 11 and 13 show a coiled body 12 with radially extending openings between the adjacent rings. It can also be seen there is a material 14 extending along the path of the coiled body forming a coiled sleeve. Razavi discloses that an anti-thrombotic drug is associated with the material, col. 3, lines 22-25. Fig. 2 shows that a delay-release

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material or biodegradable layer **16** is used on the material with the drug, col. 3, lines 12-17. Razavi also discloses the body or core coil is made of metal, col. 2, lines 37-47.

Razavi additionally discloses a sheath or sleeve can be the protective layer and pulled off upon deployment, col. 6, lines 13-16. Regarding claims 10,41,45,77, Figs. 8 and 10 show the prosthesis with spaced apart turns defining gaps in the radially expanded state.

Claims 1-6,9,19-27,43,45,48-57,59,61,62 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (5873904). Figs. 11 and 15 show a coiled body stent. Ragheb et al. disclose a stent that has spaced apart turns defining gaps when radially expanded. Ragheb discloses a drug layer with a porous covering thereon, col. 4, lines 23-32. The stent can be made from metal, such as nickel-titanium, col. 3, lines 58-59. Drugs that can be delivered via the stent include anti-inflammatories and antiproliferatives or antirestenotic agents, col. 4, lines 60-67. The porous polymer covering the drug can be PTFE, col. 5, lines 43,44,50,51. Ragheb also discloses the bioactive material or drugs can be microencapsulated, col. 19, lines 60-63. Ragheb additionally discloses the covered stent can comprise an additional protective layer or porous layer, col. 14, lines 53-54. The outer porous layer can be a polymer that is biodegradable, col. 13, lines 33-44. Ragheb also discloses the use of first and second dispensable agents, col. 5, lines 58,59,63 and col. 6, lines 3-14.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of Kropf (4760849). Razavi is explained supra. However, Razavi does not disclose the prosthesis body with longitudinal extending side members and cross members. Kropf shows a prosthesis (Fig. 5) with longitudinal extending side members and cross members. Razavi does disclose other configurations can be used for the coil body, col. 4, lines 30-31. Thus, it would have been obvious to one of ordinary skill in the art to use the design of Kropf for the coiled body of Razavi in order to provide more structural support to the vessel.

Claims 11,46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of McNamara et al. (5147370). Razavi is explained supra. However, Razavi does not disclose the prosthesis comprising turns touching one another when in the expanded state. McNamara et al. show a coil (Fig. 1) with turns touching one another when in the expanded state, see also col. 3, lines 55,56. McNamara also teaches the coil is to be designed with closely spaced turns, col. 6, lines 19-23. It would have been obvious to one of ordinary skill in the art to use a closely spaced turned coil as taught by McNamara with the coiled body of Razavi in order to provide more structural support to the vessel.

Claims 42,78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Razavi '685 in view of Ragheb et al. '904. Razavi is explained supra. Razavi does

disclose polymers can be used for material on the coil, col. 3, lines 31-54. However, Razavi does not disclose the use of porous PTFE. Ragheb teaches porous polymers, i.e. PTFE covering the drug or bioactive material controls release of the bioactive material, col. 5, lines 43,44,50,51 and col. 18, lines 53-56. It would have been obvious to one of ordinary skill in the art to use alternative polymers, such as porous PTFE, taught by Ragheb for the material of Razavi in order to provide a controlled release system.

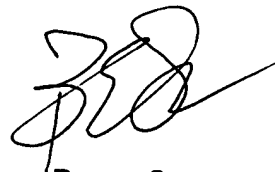
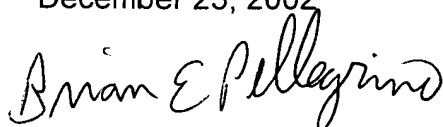
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738  
December 23, 2002



Bruce Snow

Primary Examiner